

CLAIMS

What is claimed is:

1. A process for making a pharmaceutical formulation for oral administration of an active pharmaceutical ingredient comprising applying a solution of the active pharmaceutical ingredient to form a coating on a particulate pharmaceutical substrate, wherein the substrate is free of a polysaccharide.
2. The process of claim 1, wherein the active pharmaceutical ingredient comprises a peptide pharmaceutical.
3. The process of claim 1, wherein the active pharmaceutical ingredient solution includes a material selected from the group consisting of coating agents, controlled release agents, sustained release agents, pharmaceutical excipient agents, and combinations thereof.
4. The process of claim 3, wherein the agent is selected from the group consisting of colorants, film-forming polymers, plasticizers, surfactants, permeation enhancers, buffering agents, dispersions of ethyl cellulose, coating lacquers, pigments, and combinations thereof.
5. The process of claim 1, wherein applying the active pharmaceutical ingredient solution to the particulate substrate achieves an active pharmaceutical ingredient load on the substrate ranging from about 0.1% to about 30% weight/weight.
6. The process of claim 1, wherein the substrate is selected from the group consisting of a calcium material, cellulose, and combinations thereof.
7. The process of claim 6, wherein the calcium material is selected from the group consisting of calcium carbonate, calcium citrate, dibasic calcium phosphate dihydrate, monobasic calcium phosphate, tribasic calcium phosphate, anhydrous dibasic calcium phosphate, calcium sulfate, calcium stearate, and combinations thereof.

8. The process of claim 1, further including applying another solution to form another coating.

9. The process of claim 8, wherein another solution is applied prior to applying the active pharmaceutical ingredient solution, after applying the active pharmaceutical ingredient solution, or a combination thereof.

10. The process of claim 8, wherein the other solution comprises a material selected from the group consisting of coating agents, controlled release agents, sustained release agents, pharmaceutical excipient agents, and combinations thereof.

11. The process of claim 10, wherein the agent is selected from the group consisting of colorants, film-forming polymers, plasticizers, surfactants, permeation enhancers, buffering agents, dispersions of ethyl cellulose, coating lacquers, pigments, and combinations thereof.

12. The process of claim 1, further including encapsulating the resultant in a gelatin capsule or compressing the resultant into a tablet.

13. A process for making a pharmaceutical formulation for oral administration of an active pharmaceutical ingredient comprising applying a solution of the active pharmaceutical ingredient to form a coating on a particulate calcium pharmaceutical substrate, wherein the substrate is free of a polysaccharide and the particulate calcium pharmaceutical substrate has been coated with a permeation enhancer.

14. The process of claim 13, further including applying another solution to form another coating, wherein the other solution comprises a material selected from the group consisting of coating agents, controlled release agents, sustained release agents, pharmaceutical excipient agents, and combinations thereof.

15. The process of claim 13, further including encapsulating the resultant in a gelatin capsule.

16. An oral pharmaceutical formulation comprising a particulate pharmaceutical substrate having an application of an active pharmaceutical ingredient coating, wherein the substrate is free of a polysaccharide.

17. The oral pharmaceutical formulation of claim 16, wherein the active pharmaceutical ingredient comprises a peptide pharmaceutical.

18. The oral pharmaceutical formulation of claim 16, wherein the active pharmaceutical ingredient coating includes a material selected from the group consisting of coating agents, controlled release agents, sustained release agents, pharmaceutical excipient agents, and combinations thereof.

19. The oral pharmaceutical formulation of claim 18, wherein the agent is selected from the group consisting of colorants, film-forming polymers, plasticizers, surfactants, permeation enhancers, buffering agents, dispersions of ethyl cellulose, coating lacquers, pigments, and combinations thereof.

20. The oral pharmaceutical formulation of claim 16, wherein the active pharmaceutical ingredient comprises an active pharmaceutical ingredient load on the substrate ranging from about 0.1% to about 30% weight/weight.

21. The oral pharmaceutical formulation of claim 16, wherein the substrate is selected from the group consisting of a calcium material, cellulose, and combinations thereof.

22. The oral pharmaceutical formulation of claim 21, wherein the calcium material is selected from the group consisting of calcium carbonate, calcium citrate, dibasic calcium phosphate dihydrate, monobasic calcium phosphate, tribasic calcium phosphate, anhydrous dibasic calcium phosphate, calcium sulfate, calcium stearate, and combinations thereof.

23. The oral pharmaceutical formulation of claim 16, further including another coating.

24. The oral pharmaceutical formulation of claim 23, wherein another coating is under the active pharmaceutical ingredient coating, over the active pharmaceutical ingredient coating, or a combination thereof.

25. The oral pharmaceutical formulation of claim 23, wherein the other coating comprises a material selected from the group consisting of coating agents, controlled release agents, sustained release agents, pharmaceutical excipient agents, and combinations thereof.

26. The oral pharmaceutical formulation of claim 25, wherein the agent is selected from the group consisting of colorants, film-forming polymers, plasticizers, surfactants, permeation enhancers, buffering agents, dispersions of ethyl cellulose, coating lacquers, pigments, and combinations thereof.

27. The oral pharmaceutical formulation of claim 16, wherein the particulate pharmaceutical substrate having an application of an active pharmaceutical ingredient coating is encapsulated in a gelatin capsule or is compressed into a tablet.

28. A process for making a pharmaceutical formulation for oral administration of an active pharmaceutical ingredient comprising applying a solution of the active pharmaceutical ingredient to form a coating on a particulate dibasic calcium phosphate dihydrate pharmaceutical substrate, wherein:

- (a) the application of active pharmaceutical ingredient achieves an active pharmaceutical ingredient load on the substrate ranging from about 0.1% to 30% weight/weight, and
- (b) the substrate is free of a polysaccharide and has been coated with a permeation enhancer.

29. An oral pharmaceutical formulation comprising a particulate dibasic calcium phosphate dihydrate pharmaceutical substrate having an application of an active pharmaceutical ingredient coating, wherein:

- (a) the active pharmaceutical ingredient is present in a load on the substrate ranging from about 0.1% to 30% weight/weight, and
- (b) the substrate is free of a polysaccharide and has been coated with a permeation enhancer.

30. A process for making a pharmaceutical formulation for oral administration of an insulin comprising applying a solution of the insulin to form a coating on a particulate pharmaceutical substrate.

31. The process of claim 30, wherein the insulin is selected from the group consisting of human insulin, animal insulin, and combinations thereof.

32. The process of claim 31, wherein the human insulin comprises hexyl insulin monoconjugate-2-polydisperse.

33. The process of claim 30, wherein the insulin solution includes a material selected from the group consisting of coating agents, controlled release agents, sustained release agents, pharmaceutical excipient agents, and combinations thereof.

34. The process of claim 33, wherein the agent is selected from the group consisting of colorants, film-forming polymers, plasticizers, surfactants, permeation enhancers, buffering agents, dispersions of ethyl cellulose, coating lacquers, pigments, and combinations thereof.

35. The process of claim 30, wherein applying the insulin solution to the particulate substrate achieves an insulin load on the substrate ranging from about 0.1% to about 30% weight/weight.

36. The process of claim 30, wherein the substrate is selected from the group consisting of a calcium material, cellulose, and combinations thereof.

37. The process of claim 36, wherein the calcium material is selected from the group consisting of calcium carbonate, calcium citrate, dibasic calcium phosphate dihydrate, monobasic calcium phosphate, tribasic calcium phosphate, anhydrous dibasic calcium phosphate, calcium sulfate, calcium stearate, and combinations thereof.

38. The process of claim 30, further including applying another solution to form another coating.

39. The process of claim 38, wherein another solution is applied prior to applying the insulin solution, after applying the insulin solution, or a combination thereof.

40. The process of claim 38, wherein the other solution comprises a material selected from the group consisting of coating agents, controlled release agents, sustained release agents, pharmaceutical excipient agents, and combinations thereof.

41. The process of claim 40, wherein the agent is selected from the group consisting of colorants, film-forming polymers, plasticizers, surfactants, permeation enhancers, buffering agents, dispersions of ethyl cellulose, coating lacquers, pigments, and combinations thereof.

42. The process of claim 30, further including encapsulating the resultant in a gelatin capsule or compressing the resultant into a tablet.

43. A pharmaceutical formulation for oral administration of insulin comprising a particulate pharmaceutical substrate having an application of an insulin coating, wherein the particulate pharmaceutical substrate is free of a polysaccharide.

44. The oral pharmaceutical formulation of claim 43, wherein the insulin coating includes a material selected from the group consisting of coating agents, controlled release agents, sustained release agents, pharmaceutical excipient agents, and combinations thereof.

45. The oral pharmaceutical formulation of claim 44, wherein the agent is selected from the group consisting of colorants, film-forming polymers, plasticizers, surfactants, permeation enhancers, buffering agents, dispersions of ethyl cellulose, coating lacquers, pigments, and combinations thereof.

46. The oral pharmaceutical formulation of claim 43, wherein the insulin comprises an insulin load on the substrate ranging from about 0.1% to about 30% weight/weight.

47. The oral pharmaceutical formulation of claim 43, wherein the substrate is selected from the group consisting of a calcium material, cellulose, and combinations thereof.

48. The oral pharmaceutical formulation of claim 47, wherein the calcium material is selected from the group consisting of calcium carbonate, calcium citrate, dibasic calcium phosphate dihydrate, monobasic calcium phosphate, tribasic calcium phosphate, anhydrous dibasic calcium phosphate, and combinations thereof.

49. The oral pharmaceutical formulation of claim 43, further including another coating.

50. The oral pharmaceutical formulation of claim 49, wherein another coating is under the insulin coating, over the insulin coating, or a combination thereof.

51. The oral pharmaceutical formulation of claim 49, wherein the other coating comprises a material selected from the group consisting of coating agents, controlled release agents, sustained release agents, pharmaceutical excipient agents, and combinations thereof.

52. The oral pharmaceutical formulation of claim 51, wherein the agent is selected from the group consisting of colorants, film-forming polymers, plasticizers, surfactants, permeation

enhancers, buffering agents, dispersions of ethyl cellulose, coating lacquers, pigments, and combinations thereof.

53. The oral pharmaceutical formulation of claim 43, wherein the particulate pharmaceutical substrate having an application of an insulin coating is encapsulated in a gelatin capsule or is compressed into a tablet.

54. A process for making a pharmaceutical formulation for oral administration of an insulin comprising applying a solution of an insulin to form a coating on a particulate dibasic calcium phosphate dihydrate pharmaceutical substrate, wherein:

- (a) the application of the insulin achieves an insulin load on the substrate ranging from about 0.1% to 30% weight/weight, and
- (b) the substrate is free of a polysaccharide and has been coated with a permeation enhancer.

55. An oral pharmaceutical formulation of insulin comprising a particulate dibasic calcium phosphate dihydrate pharmaceutical substrate having an application of an insulin coating, wherein:

- (a) the insulin is present in a load on the substrate ranging from about 0.1% to 30% weight/weight, and
- (b) the substrate is free of a polysaccharide and has been coated with a permeation enhancer.